AMENDED CLAIMS

[Received by the International Bureau on 24 August 2005 (24.08.05)
original claims unchanged ; new claims 7-14 added]

7. A method of preventing nosocomial infections, comprising:

applying a disinfectant to an area of the patient's mucosa, wherein the disinfectant comprises chlorhexadine gluconate;

inserting an endotracheal tube into the patient's trachea such that it is in contact with the area of the patient's mucosa.

8. The method of claim 7, wherein the area of the patient's mucosa is at least one selected from the group consisting of the gingiva, the buccal mucosa, the floor of the mouth, the hard palate, the soft palate, the dorsal tongue, the lateral tongue, the ventral tongue, and an oropharyngeal surface.

9. The method of claim 7, wherein the step of applying a disinfectant comprises contacting a swab applicator with the disinfectant and contacting the area of the patient's mucosa with the swab applicator.

10. The method of claim 7, further comprising providing a spray can containing the disinfectant, and wherein the step of applying a disinfectant comprises spraying the disinfectant on the area of the patient's mucosa.

11. A method of preventing nosocomial infections, comprising:

providing a swab applicator comprising a handle having a frangible tip and a sponge disposed about the frangible tip, wherein the handle contains a disinfectant comprising chlorhexadine gluconate;

separating at least a portion of the tip from the handle such that the disinfectant contacts the sponge; and

contacting an area of the patient's mucosa with the sponge.

12. The method of claim 11, wherein the frangible tip is scored.

13. The method of claim 11, further comprising inserting an endotracheal tube into the patient's trachea such that is in contact with the area of the patient's mucosa.

14. The method of claim 11, wherein the area of the patient's mucosa is at least one selected from the group consisting of the gingiva, the buccal mucosa, the floor of the mouth, the hard palate, the soft palate, the dorsal tongue, the lateral tongue, the ventral tongue, and an oropharyngeal surface.

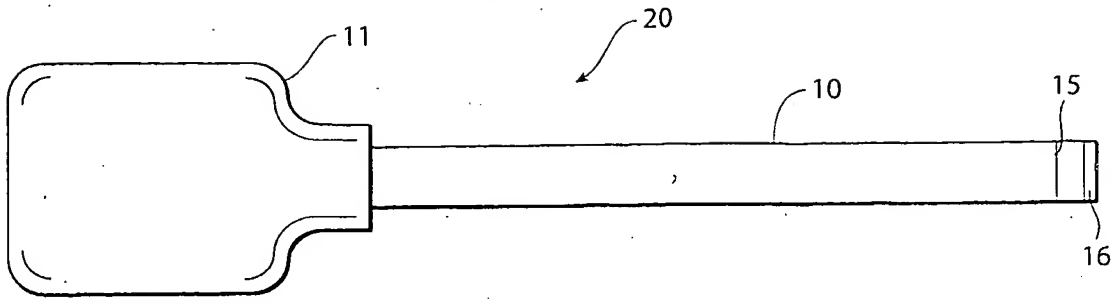

FIG. 1

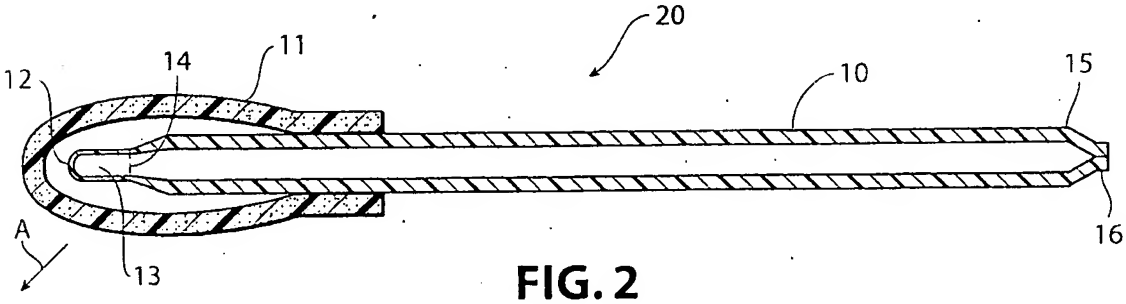

FIG. 2

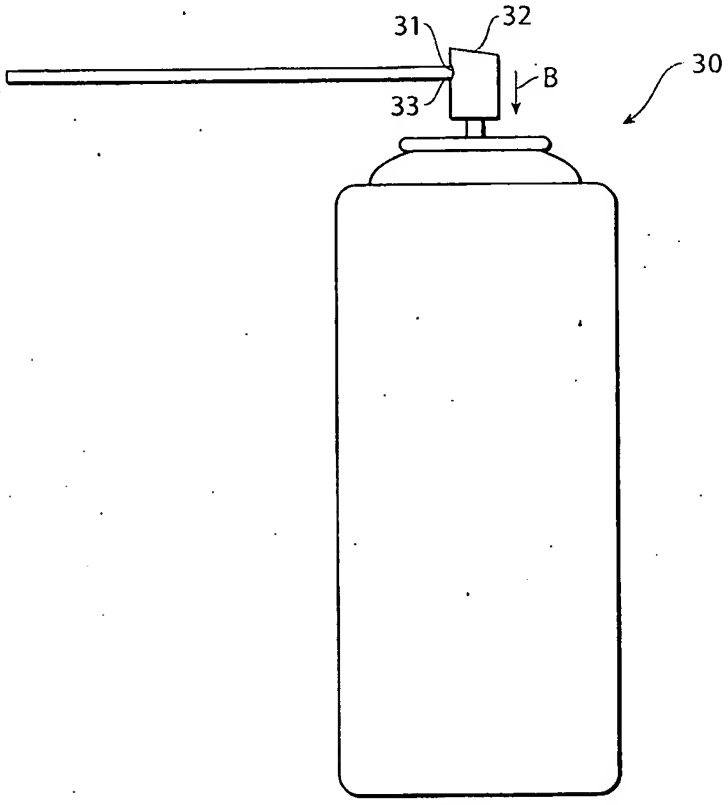

FIG. 3

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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DRUMMOND & DUCKWORTH
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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing (*day/month/year*)	15FEB2005
Applicant's or agent's file reference 344-P-48-PCT	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/US04/36362	01 November 2004 (01.11.2004)	

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61K 9/00, 31/205 and US Cl.: 424/400; 514/554

Applicant

BARSHIS, DAVID

1. This opinion contains indications relating to the following items:

- [X] Box No. I — Basis of the opinion
- [ ] Box No. II — Priority
- [ ] Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV — Lack of unity of invention
- [X] Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI — Certain documents cited
- [ ] Box No. VII — Certain defects in the international application
- [ ] Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(*b*) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	M. Haghighatian J. Roberts for Telephone No. 571-272-1600

Form PCT/ISA/237 (cover sheet) (January 2004)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/36362

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/36362

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims NONE	YES
	Claims 1-6	NO
Inventive step (IS)	Claims NONE	YES
	Claims 1-6	NO
Industrial applicability (IA)	Claims 1-6	YES
	Claims NONE	NO

2. Citations and explanations:

Claims 1-6 lack novelty under PCT Article 33(2) as being anticipated by Grayson et al (2004/0191274 A1). Grayson teaches topical compositions comprising at least one anti-microbial agent, which is preferably chlorhexidine gluconate (see [0033]). Grayson also discloses that the said formulation may be in a spray form, aerosol form or be incorporated in a swab or sponge. The formulation may be applied to any part of the body excluding the mucous membranes (see [0050] and [0059]). The said topical composition is useful as an antiseptic and/or disinfecting agent in many environments including hospitals (see [0052]).

Claims 1, 4-6 lack novelty under PCT Article 33(2) as being anticipated by Purdue Frederick (1993, 2004). The PDR document discloses that Betasept® is a chlohexidine gluconate 4% scrub which can be used for various disinfecting needs, such as wound and skin cleansing. The product is available in bottles with pump.

Claim 1 lacks novelty under PCT Article 33(2) as being anticipated by Purdue Frederick (1991, 2004). The PDR document discloses that Betadine ® is a povidone-iodine 7.5% which is used for antiseptic purposes and is provided in plastic bottles.

Claims 2-3 lack an inventive step under PCT Article 33(3) as being obvious over Purdue Frederick (1993, 2004). The PDR document discloses that Betasept® is a chlohexidine gluconate 4% scrub which can be used to disinfect skin. Betasept® is said to be available in bottles but lacks specific disclosure on its use as a spray or swab. However it would have been obvious to one of ordinary skill in the art that such products are best used with a sterile swab or through a spray bottle to eliminate contamination.

Claims 2-3 lack an inventive step under PCT Article 33(3) as being obvious over Purdue Frederick (1991, 2004). The PDR document discloses that Betadine ® is a povidone-iodine 7.5% which is used for antiseptic purposes and is provided in plastic bottles. Betadine® is said to be available in bottles but lacks specific disclosure on its use as a spray or swab. However it would have been obvious to one of ordinary skill in the art that such products are best used with a sterile swab or through a spray bottle to eliminate contamination.

Claims 1-6 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.